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Anand et al.

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(54) **SPINAL CORRECTION METHOD AND SYSTEM**

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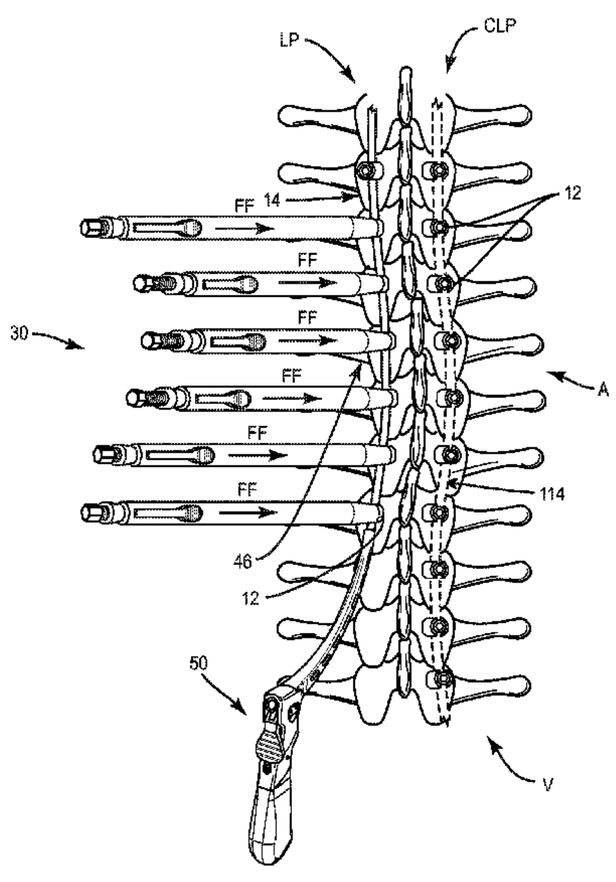
Primary Examiner — Jan Christopher Merene

(57) **ABSTRACT**

A method for treating a spine comprises the steps of: fastening a plurality of fasteners with a lateral portion of vertebrae, each of the fasteners including a first element that defines an implant cavity and a second element configured for penetrating the vertebrae; providing a longitudinal element including a portion having a selected curvature; disposing the longitudinal element with the implant cavities such that the portion is disposed in a selected orientation relative to the vertebrae; and moving a first element of at least one of the fasteners relative to the portion such that a second element of the at least one of the fasteners derotates the vertebrae while maintaining the portion in the selected orientation. Systems and implants are disclosed.

20 Claims, 7 Drawing Sheets



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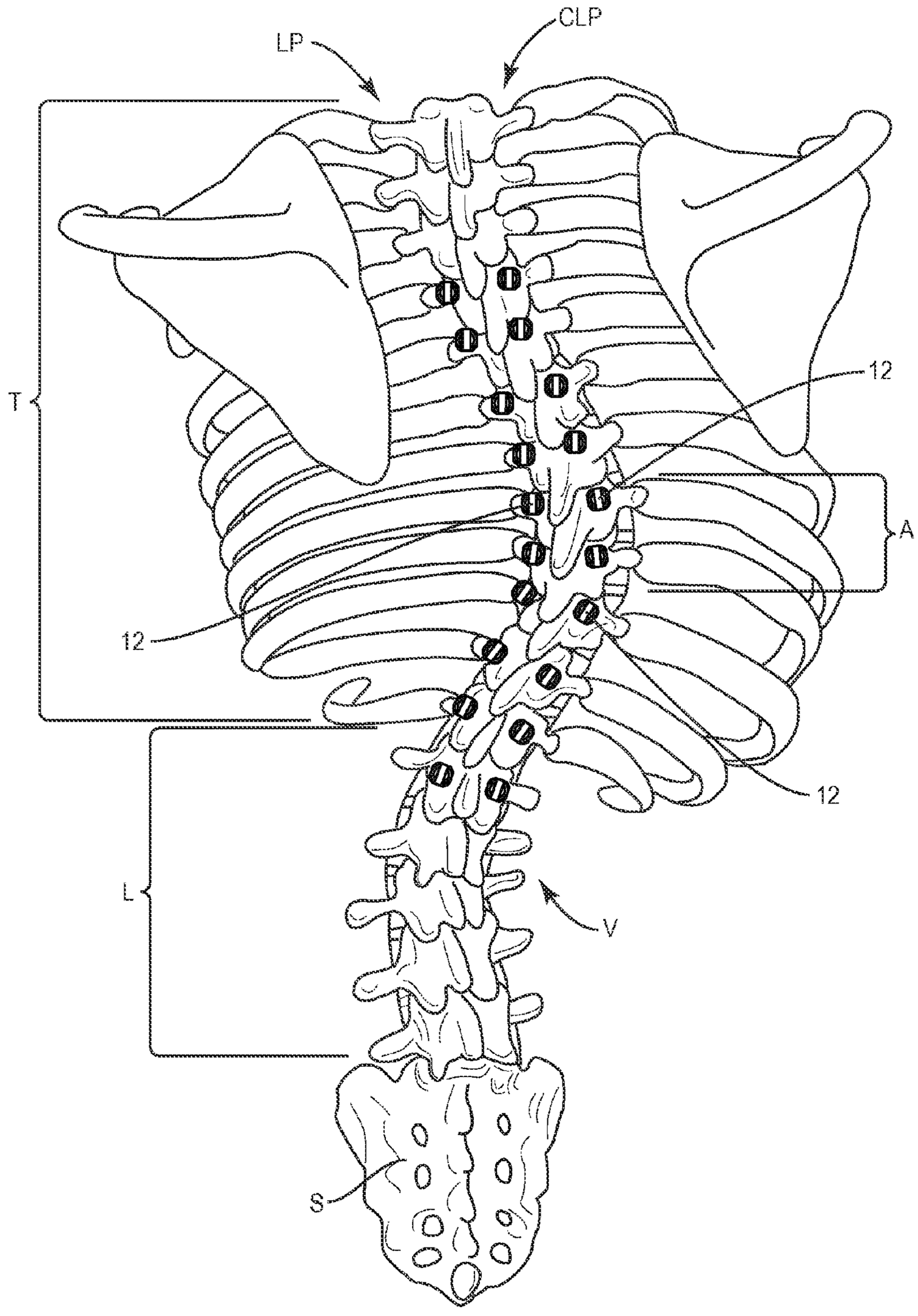

FIG. 1

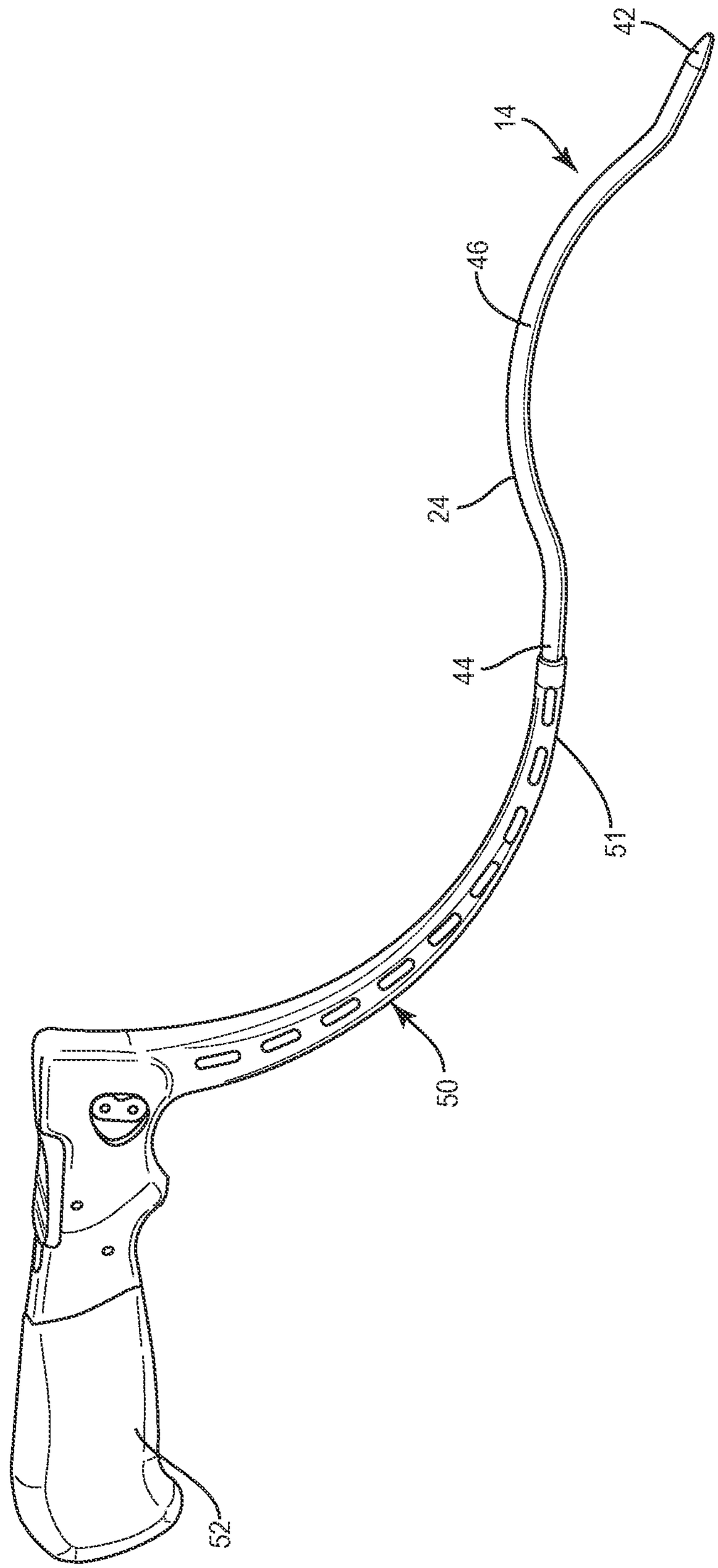

FIG. 2

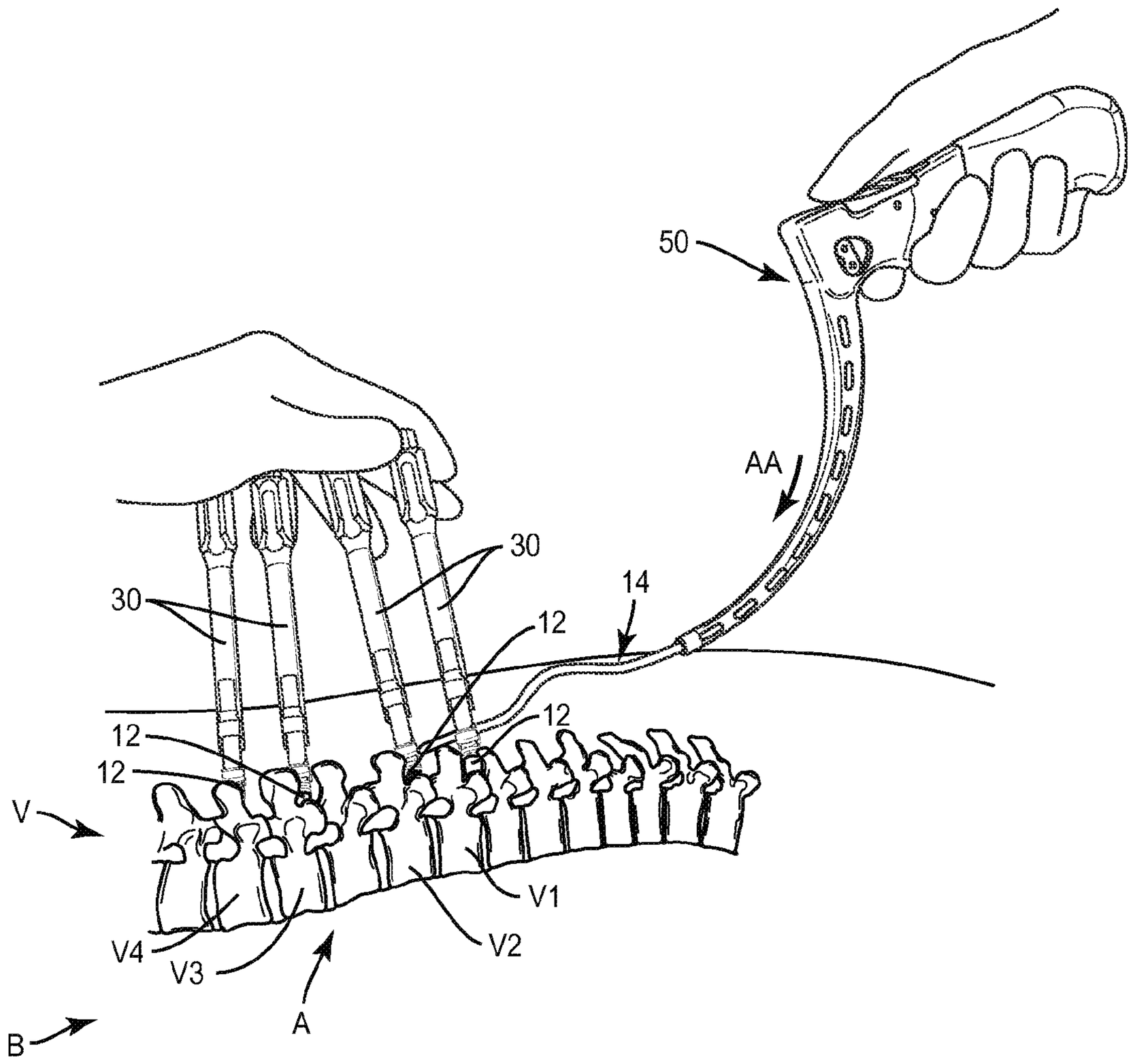

FIG. 3

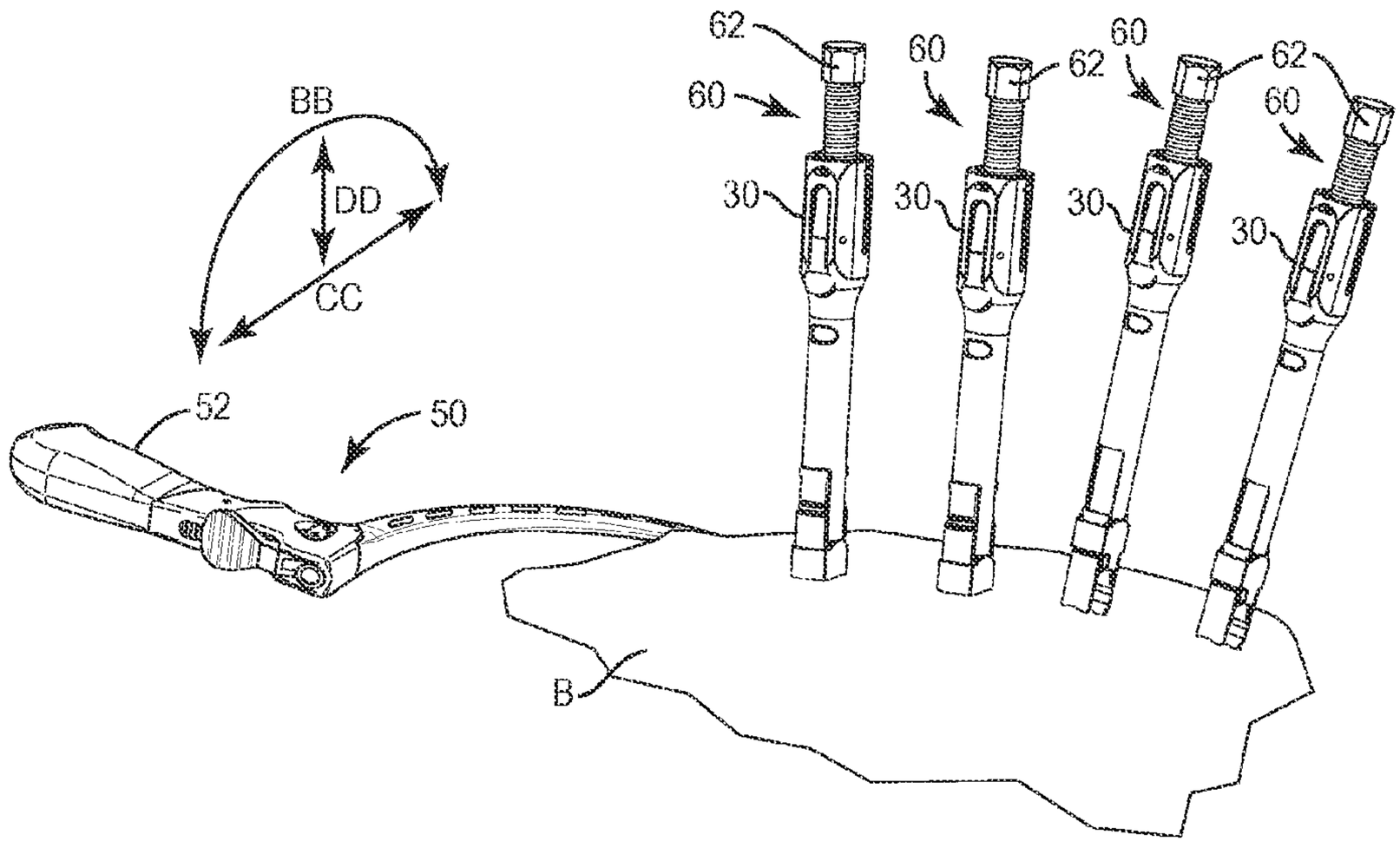

FIG. 4

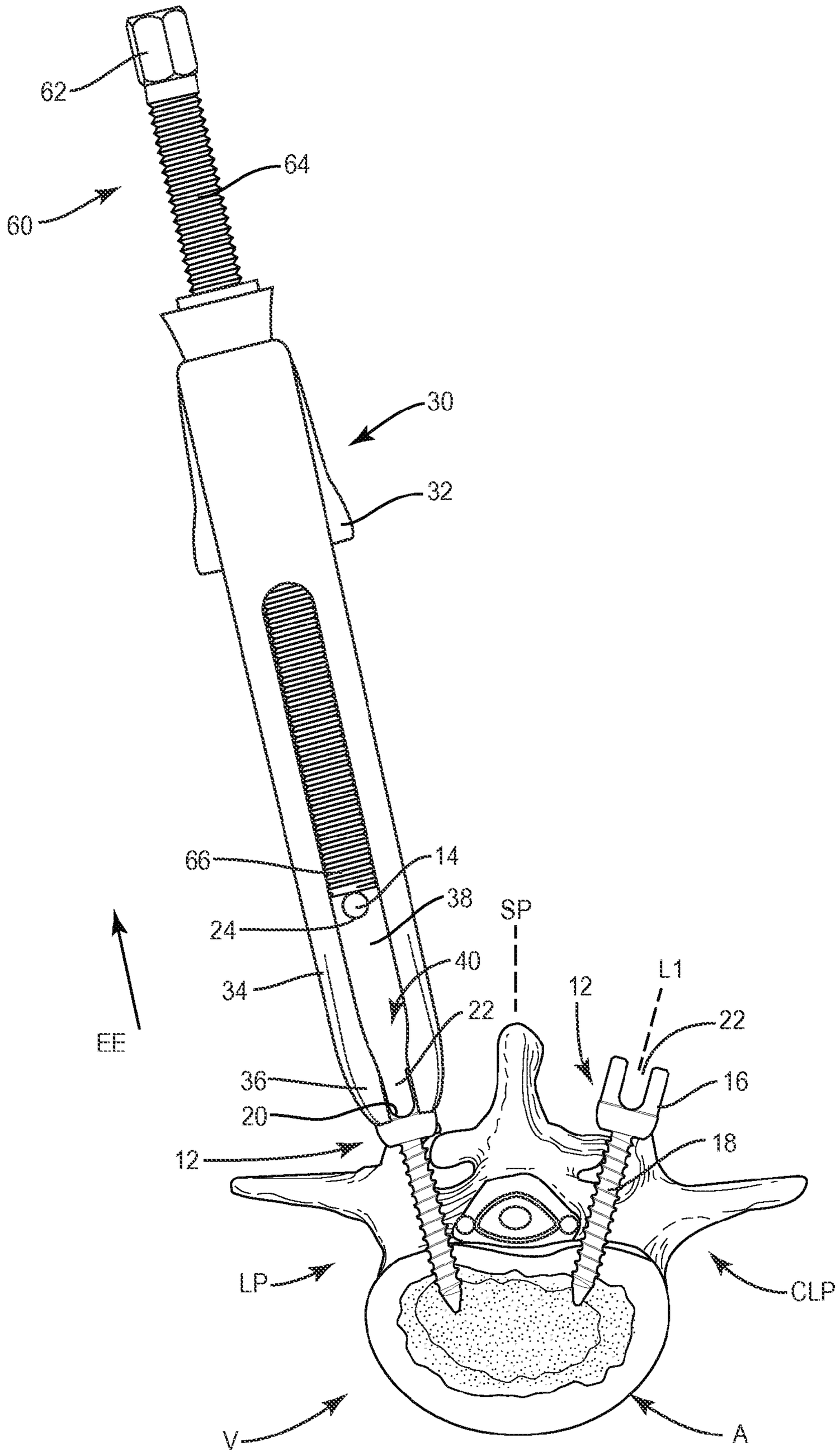
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FIG. 5

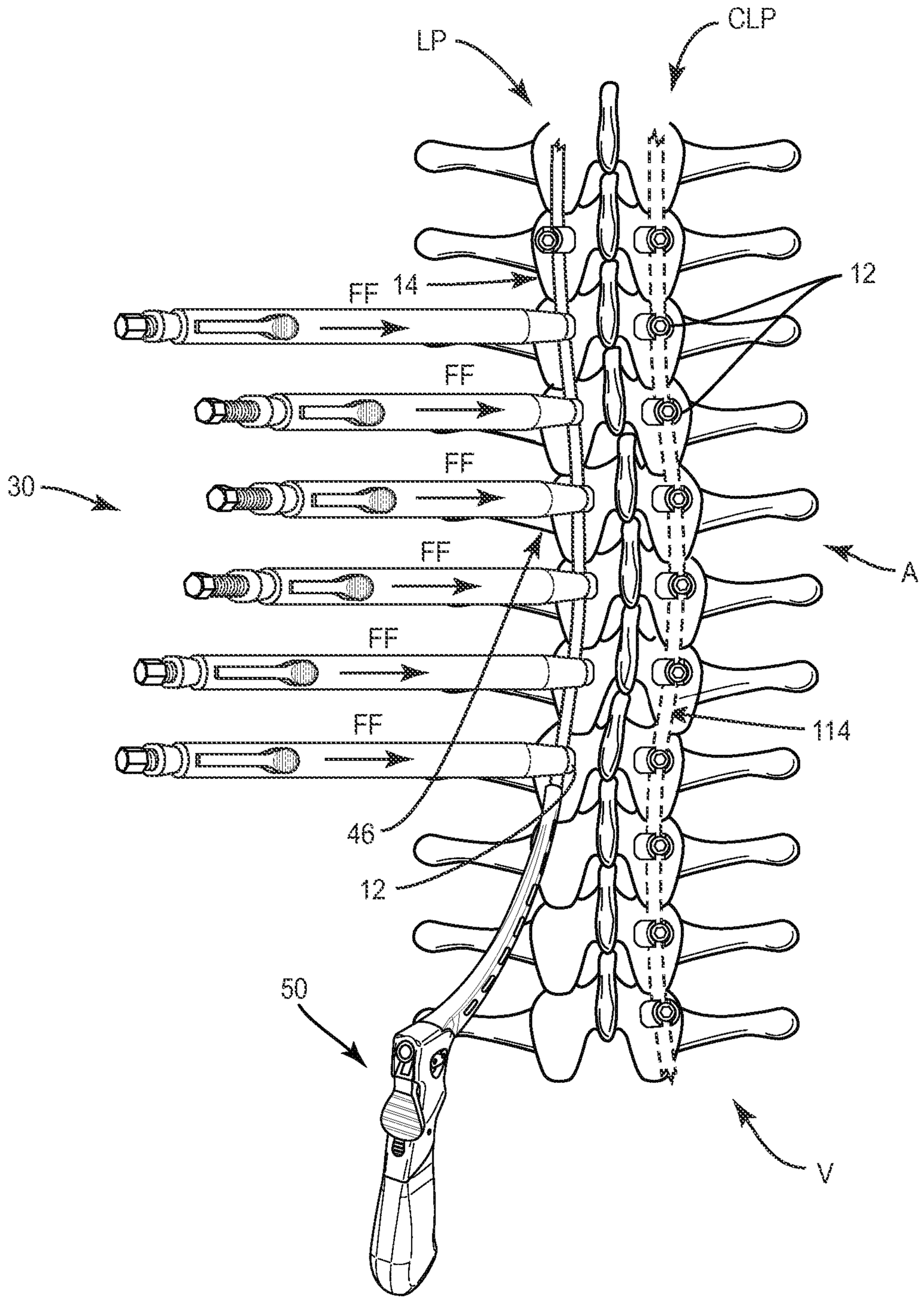

FIG. 6

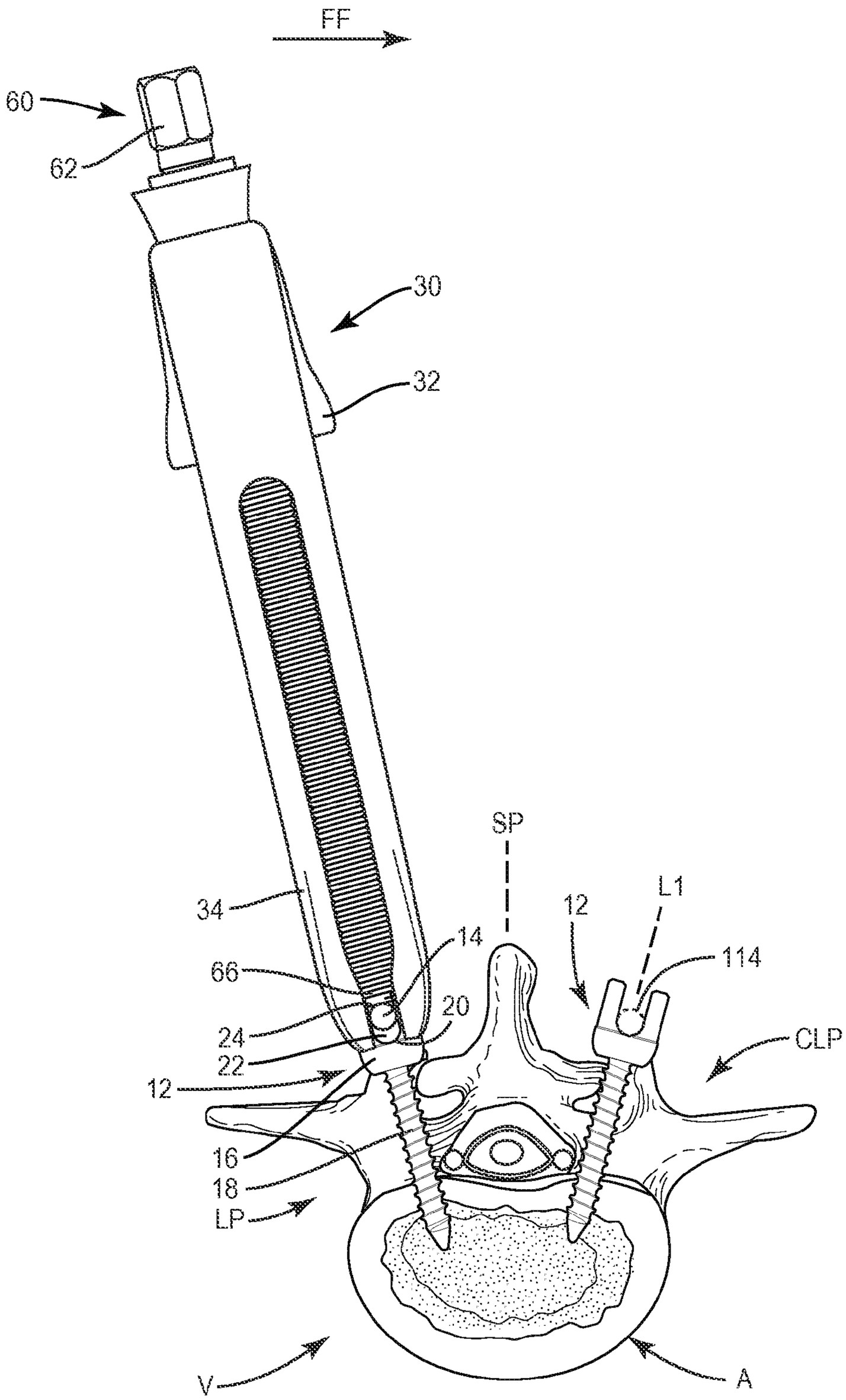

FIG. 7

SPINAL CORRECTION METHOD AND SYSTEM

TECHNICAL HELD

The present disclosure generally relates to medical devices for the treatment of musculoskeletal disorders, and more particularly to a surgical system and method for correction of a spine disorder.

BACKGROUND

Spinal pathologies and disorders such as scoliosis and other curvature abnormalities, kyphosis, degenerative disc disease, disc herniation, osteoporosis, spondylolisthesis, stenosis, tumor, and fracture may result from factors including trauma, disease and degenerative conditions caused by injury and aging. Spinal disorders typically result in symptoms including deformity, pain, nerve damage, and partial or complete loss of mobility.

Non-surgical treatments, such as medication, rehabilitation and exercise can be effective, however, may fail to relieve the symptoms associated with these disorders. Surgical treatment of these spinal disorders includes correction, fusion, fixation, discectomy, laminectomy and implantable prosthetics. Correction treatments may employ implants that are manipulated for engagement with vertebrae to position and align one or more vertebrae. This disclosure describes an improvement over these prior art technologies.

SUMMARY

In one embodiment, a method for treating a spine is provided. The method comprising the steps of; fastening a plurality of fasteners with a lateral portion of vertebrae, each of the fasteners including a first element that defines an implant cavity and a second element configured for penetrating the vertebrae; providing a longitudinal element including a portion having a selected curvature; disposing the longitudinal element with the implant cavities such that the portion is disposed in a selected orientation relative to the vertebrae; and moving a first element of at least one of the fasteners relative to the portion such that a second element of the at least one of the fasteners derotates the vertebrae while maintaining the portion in the selected orientation. In some embodiments, implants and systems are disclosed.

In one embodiment, the method comprises the steps of: fastening a plurality of fasteners with a lateral portion of vertebrae, each of the fasteners including a receiver that defines an implant cavity and a shaft configured for penetrating the vertebrae; providing a longitudinal element including a portion having a selected curvature; connecting a surgical instrument to the longitudinal element; manipulating the surgical instrument to pass the longitudinal element through the implant cavities; reducing the longitudinal element with at least one implant cavity such that the portion is disposed in a selected orientation relative to the vertebrae; and rotating a receiver of at least one of the fasteners relative to the portion such that a shaft of the at least one of the fasteners derotates the vertebrae while maintaining the portion in the selected orientation.

In one embodiment, the method comprises the steps of: fastening a plurality of fasteners with a lateral portion of vertebrae, each of the fasteners including a receiver that defines an implant cavity and a shaft configured for penetrating the vertebrae, wherein one or more of the fasteners

are fastened with an apical portion of the vertebrae; providing a longitudinal element including a portion having a selected curvature; reducing the longitudinal element with the fasteners disposed with the apical portion such that the portion is disposed in a selected orientation relative to the vertebrae; moving the receivers relative to the portion such that the shafts derotate the vertebrae while maintaining the portion in the selected orientation; and subsequently reducing the longitudinal element with the remaining fasteners sequentially from the apical portion in a cephalad and/or a caudal orientation.

BRIEF DESCRIPTION OF THE DRAWINGS

The present disclosure will become more readily apparent from the specific description accompanied by the following drawings, in which:

FIG. **1** is a plan view of components of one embodiment of a system in accordance with the principles of the present disclosure disposed with vertebrae of a body;

FIG. **2** is a perspective view of components of one embodiment of a system in accordance with the principles of the present disclosure;

FIG. **3** is a side view of the components of the system and the body shown in FIGS. **1** and **2**;

FIG. **4** is a perspective view of components of the system and the body shown in FIG. **3**;

FIG. **5** is an axial view of components of the system and vertebrae shown in FIG. **3**;

FIG. **6** is a plan view of components of the system and vertebrae shown in FIG. **3**; and

FIG. **7** is an axial view of components of the system and vertebrae shown in FIG. **3**.

DETAILED DESCRIPTION

The exemplary embodiments of the spinal correction system and related methods of use disclosed are discussed in terms of medical devices for the treatment of musculoskeletal disorders and more particularly, in terms of a spinal correction system and method that facilitates connection of at least one implant with vertebrae to position and align one or more vertebrae for treatment of a spine. In some embodiments, the spinal correction system can include instruments such as extenders, reducers and translators, which can be used to introduce a vertebral construct such as a rod to a bone fastener, such as a bone anchor or bone screw. For example, an instrument can include an extender having bone anchor attachment features on one or both sides of the instrument. In some embodiments, the extender may be used with or include a reducer assembly to introduce a spinal rod into a bone fastener.

In one embodiment, a method for spinal correction is provided with a system for posterior screw and rod placement and manipulation for deformity correction. The method includes use of multi-axial or poly-axial pedicle screws placed minimally invasively with a removable slotted extension that guides placement of a longitudinal rod with a selected sagittal curve to control spine curvature in lower thoracic and lumbar regions. In one embodiment, the method employs minimally invasive direct lateral interbody techniques that allow coronal plane deformity correction prior to posterior screw/rod placement. In some embodiments, interbody implants, bone screws and spinal rods are provided as a stable construct for deformity correction and fusion.

In one embodiment, the method allows direct correction of a sagittal plane deformity through contouring of one or more spinal rods. In one embodiment, the method provides coronal plane deformity correction by maintaining the sagittal plane curvature of the spinal rods parallel to the sagittal plane after rod placement through screw extensions. The spinal rods are reduced vertically through screw extenders and a screw head of the poly-axial screws are pivoted around an outer surface of the spinal rods to provide coronal plane correction and/or provide derotation of vertebral bodies.

In one embodiment, the system is employed with a method for deformity correction, such as, for example, correction of an adolescent idiopathic scoliosis using a construct of implants including fasteners, such as, for example, multi-axial pedicle screws, and manipulating the implants using implant supports, such as, for example, reduction instruments. In one embodiment, the system is employed with a method for deformity correction, such as, for example, correction of a lumbar scoliosis. In some embodiments, the system is employed with a method and sequence to efficiently correct various deformity pathologies in sagittal, coronal and axial planes of vertebrae by using screws and reduction instruments.

In some embodiments, vertebrae can be derotated using surgical instruments and fasteners as a lever prior to final tightening of set screws with the fasteners. For example, this derotation can be performed initially at the apex of a disorder and then cephalad and caudal from a mid-portion of a pre-formed spinal rod. Such derotation can be performed segmentally and/or prior to final tightening.

In some embodiments, the system is employed for axial derotation of vertebral bodies to improve chest wall volume and pulmonary function. In one embodiment, the system includes pedicle screws placed in the vertebral bodies that provide anchors for spinal manipulation. In one embodiment, the system includes implant supports, such as, for example, reduction instruments attached to the pedicle screws that are configured as derotation levers and can be linked together to distribute derotation forces applied to components of the system. In some embodiments, the spinal correction system may include instruments that are connected or attached to an instrument(s) such as, for example, a lateral translation handle or derotation instruments.

In some embodiments, the method is used with surgical navigation, such as, for example, fluoroscope or image guidance. In one embodiment, one or all of the components of the surgical system are disposable, peel-pack, pre-packed sterile devices. One or all of the components of the surgical system may be reusable. The surgical system may be configured as a kit with multiple sized and configured components.

In one embodiment, the present disclosure may be employed to treat spinal disorders such as, for example, degenerative disc disease, disc herniation, osteoporosis, spondylolisthesis, stenosis, scoliosis and other curvature abnormalities, kyphosis, tumor and fractures. In one embodiment, the present disclosure may be employed with other osteal and bone related applications, including those associated with diagnostics and therapeutics. In some embodiments, the disclosed surgical system and methods may be alternatively employed in a surgical treatment with a patient in a prone, supine position, lateral and/or employ various surgical approaches to the spine, including anterior, posterior, posterior mid-line, direct lateral, postero-lateral, and/or antero-lateral approaches, and in other body regions.

The present disclosure may also be alternatively employed with procedures for treating the lumbar, cervical, thoracic, sacral and pelvic regions of a spinal column. The system and methods of the present disclosure may also be used on animals, bone models and other non-living substrates, such as, for example, in training, testing and demonstration.

The present disclosure may be understood more readily by reference to the following detailed description of the embodiments taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this application is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting. Also, as used in the specification and including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment. It is also understood that all spatial references, such as, for example, horizontal, vertical, top, upper, lower, bottom, left and right, are for illustrative purposes only and can be varied within the scope of the disclosure. For example, the references "upper" and "lower" are relative and used only in the context to the other, and are not necessarily "superior" and "inferior".

Further, as used in the specification and including the appended claims, "treating" or "treatment" of a disease or condition refers to performing a procedure that may include administering one or more drugs to a patient (human, normal or otherwise or other mammal), employing implantable devices, and/or employing instruments that treat the disease, such as, for example, micro discectomy instruments used to remove portions bulging or herniated discs and/or bone spurs, in an effort to alleviate signs or symptoms of the disease or condition. Alleviation can occur prior to signs or symptoms of the disease or condition appearing, as well as after their appearance. Thus, treating or treatment includes preventing or prevention of disease or undesirable condition (e.g., preventing the disease from occurring in a patient, who may be predisposed to the disease but has not yet been diagnosed as having it). In addition, treating or treatment does not require complete alleviation of signs or symptoms, does not require a cure, and specifically includes procedures that have only a marginal effect on the patient. Treatment can include inhibiting the disease, e.g., arresting its development, or relieving the disease, e.g., causing regression of the disease. For example, treatment can include reducing acute or chronic inflammation; alleviating pain and mitigating and inducing re-growth of new ligament, bone and other tissues; as an adjunct in surgery; and/or any repair procedure. Also, as used in the specification and including the appended claims, the term "tissue" includes soft tissue, ligaments, tendons, cartilage and/or bone unless specifically referred to otherwise.

The following discussion includes a description of a surgical system and related methods of employing the surgical system in accordance with the principles of the present disclosure. Alternate embodiments are also disclosed. Reference will now be made in detail to the exemplary embodi-

ments of the present disclosure, which are illustrated in the accompanying figures. Turning to FIGS. **1-7**, there are illustrated components of a surgical system, such as, for example, a spinal correction system **10**.

The components of spinal correction system **10** can be fabricated from biologically acceptable materials suitable for medical applications, including metals, synthetic polymers, ceramics and bone material and/or their composites, depending on the particular application and/or preference of a medical practitioner. For example, the components of spinal correction system **10**, individually or collectively, can be fabricated from materials such as stainless steel alloys, commercially pure titanium, titanium alloys, Grade 5 titanium, superelastic titanium alloys, cobalt-chrome alloys, stainless steel alloys, superelastic metallic alloys (e.g., Nitinol, super elasto-plastic metals, such as GUM METAL® manufactured by Toyota Material Incorporated of Japan), ceramics and composites thereof such as calcium phosphate (e.g., SKELITE™ manufactured by Biologix Inc), thermoplastics such as polyaryletherketone (PAEK) including polyetheretherketone (PEEK), polyetherketoneketone (PEKK) and polyetherketone (PEK), carbon-PEEK composites, PEEK-$BaSO_4$ polymeric rubbers, polyethylene terephthalate (PET), fabric, silicone, polyurethane, silicone-polyurethane copolymers, polymeric rubbers, polyolefin rubbers, hydrogels, semi-rigid and rigid materials, elastomers, rubbers, thermoplastic elastomers, thermoset elastomers, elastomeric composites, rigid polymers including polyphenylene, polyamide, polyimide, polyetherimide, polyethylene, epoxy, bone material including autograft, allograft, xenograft or transgenic cortical and/or corticocancellous bone, and tissue growth or differentiation factors, partially resorbable materials, such as, for example, composites of metals and calcium-based ceramics, composites of PEEK and calcium based ceramics, composites of PEEK with resorbable polymers, totally resorbable materials, such as, for example, calcium based ceramics such as calcium phosphate such as hydroxyapatite (HA), corraline HA, biphasic calcium phosphate, tricalcium phosphate, or fluorapatite, tri-calcium phosphate (TCP), HA-TCP, calcium sulfate, or other resorbable polymers such as polyaelide, polyglycolide, polyiyrosine carbonate, polycaroplaetohe and their combinations, biocompatible ceramics, mineralized collagen, bioactive glasses, porous metals, bone particles, bone fibers, morselized bone chips, bone morphogenetic proteins (BMP), such as BMP-2, BMP-4, BMP-7, rhBMP-2, or rhBMP-7, demineralized bone matrix (DBM), transforming growth factors (TGF, e.g., TGF-β), osteoblast cells, growth and differentiation factor (GDF), insulin-like growth factor 1, platelet-derived growth factor, fibroblast growth factor, or any combination thereof.

Various components of spinal correction system **10** may have material composites, including the above materials, to achieve various desired characteristics such as strength, rigidity, elasticity, compliance, biomechanical performance, durability and radiolucency or imaging preference. The components of spinal correction system **10**, individually or collectively, may also be fabricated from a heterogeneous material such as a combination of two or more of the above-described materials. The components of spinal correction system **10** may be monolithically formed, integrally connected or include fastening elements and/or instruments, as described herein.

Spinal correction system **10** is employed, for example, with a minimally invasive procedure, including percutaneous techniques, and mini-open surgical techniques to deliver and introduce instrumentation and/or an implant, such as, for example, a bone fastener, for a correction treatment at a surgical site within a body of a patient, for example, a section of a spine to treat various spine pathologies, such as, for example, adolescent idiopathic scoliosis and Scheuermann's kyphosis. In some embodiments, spinal correction system **10** may comprise various instruments, such as, for example, inserters, reducers, spreaders, distracters, blades, clamps, forceps, elevators and drills, which may be alternately sized and dimensioned, and arranged as a kit.

Spinal correction system **10** includes a fastener, such as, for example, a poly-axial or multi-axial bone screw (MAS) **12**, as shown in FIG. **1**, that connects a longitudinal element, such as, for example, a spinal rod **14**, as shown in FIG. **2**, to tissue, such as, for example, vertebrae V and/or components of spinal correction system **10**, such as, for example, connectors, plates and other constructs, as will be described. Each MAS **12** defines a longitudinal axis L**1**, as shown in FIG. **5**. MAS **12** comprises a first element, such as, for example, a receiver **16** and a second element, such as, for example, an elongated shaft **18** configured for penetrating tissue.

Shaft **18** has a cylindrical cross section configuration and includes an outer surface having an external thread form. In some embodiments, the external thread form may include a single thread turn or a plurality of discrete threads. In some embodiments, other engaging structures may be located on shaft **18**, such as, for example, a nail configuration, barbs, expanding elements, raised elements and/or spikes to facilitate engagement of shaft **18** with tissue, such as, for example, vertebrae V.

In some embodiments, all or only a portion of shaft **18** may have alternate cross section configurations, such as, for example, oval, oblong, triangular, square, polygonal, irregular, uniform, non-uniform, offset, staggered, undulating, arcuate, variable and/or tapered. In some embodiments, the outer surface of shaft **18** may include one or a plurality of openings. In some embodiments, all or only a portion of the outer surface of shaft **18** may have alternate surface configurations to enhance fixation with tissue such as, for example, rough, arcuate, undulating, mesh, porous, semi-porous, dimpled and/or textured. In some embodiments, all or only a portion of shaft **18** may be disposed at alternate orientations, relative to the longitudinal axis, such as, for example, transverse, perpendicular and/or other angular orientations such as acute or obtuse, co-axial and/or may be offset or staggered. In some embodiments, all or only a portion of shaft **18** may be cannulated.

Receiver **16** includes a pair of spaced apart arms having an inner surface **20** that defines an implant cavity, such as, for example, a U-shaped passageway **22**. Passageway **22** is configured for disposal of an implant, such as, for example, spinal rod **14**. In some embodiments, all or only a portion of passageway **22** may have alternate cross section configurations, such as, for example, oval, oblong, triangular, square, polygonal, irregular, uniform, non-uniform, offset, staggered, and/or tapered. In some embodiments, the arms of receiver **16** may be disposed at alternate orientations, relative to axis L**1**, such as, for example, transverse, perpendicular and/or other angular orientations such as acute or obtuse, co-axial and/or may be offset or staggered.

In one embodiment, as shown in FIGS. **1-7**, MAS **12** has a multi axial configuration such that receiver **16** is rotatable to a selected angle through and within an angular range relative to axis L**1** in a plurality of planes that lie in a cone configuration. The area and/or volume defined by the cone configuration is defined by the range of motion of receiver **16** about axis L**1**. In one embodiment, a receiver **16** is

movable relative to a shaft **18** of at least one MAS **12** to derotate vertebrae V. In one embodiment, receiver **16** is rotated and/or pivoted relative to a shaft **18** of at least one MAS **12** such that inner surface **20** rotates about and relative to an outer surface **24** of spinal rod **14** to provide coronal plane correction and/or provide derotation of vertebral levels of vertebrae V, which include at least an apical portion A of a scoliosis curvature of vertebrae V, as shown in FIG. **1**. Inner surface **20** includes a thread form configured for engagement with a coupling member (not shown), such as, for example, a set screw. The set screw is threaded with receiver **16** to attach, provisionally fix and/or lock spinal rod **14** with MAS **12**, as described.

In some embodiments, spinal correction system **10** includes one or more of fasteners that may be engaged with tissue in various orientations, such as, for example, series, parallel, offset, staggered and/or alternate vertebral levels. In some embodiments, the fasteners may comprise sagittal angulation screws, pedicle screws, mono-axial screws, uni-planar screws, facet screws, fixed screws, tissue penetrating screws, conventional screws, expanding screws, wedges, anchors, buttons, dips, snaps, friction fittings, compressive fittings, expanding rivets, staples, nails, adhesives, posts, fixation plates and/or posts.

Spinal rod **14** has a cylindrical cross section configuration. In some embodiments, spinal correction system **10** may include one or a plurality of spinal rods, which may be relatively disposed in a side by side, irregular, uniform, non-uniform, offset and/or staggered orientation or arrangement. In some embodiments, spinal rod **14** can have a uniform thickness/diameter. In some embodiments, spinal rod **14** may have various surface configurations, such as, for example, rough, threaded for connection with surgical instruments, arcuate, undulating, dimpled, polished and/or textured. In some embodiments, the thickness defined by spinal rod **14** may be uniformly increasing or decreasing, or have alternate diameter dimensions along its length. In some embodiments, spinal rod **14** may have various cross section configurations, such as, for example, oval, oblong, triangular, rectangular, square, polygonal, irregular, uniform, non-uniform, variable and/or tapered. In some embodiments, spinal rod **14** may have various lengths. In some embodiments, the longitudinal element may include one or a plurality of tethers.

In some embodiments, the longitudinal element may have a flexible configuration and fabricated from materials, such as, for example, polyester, polyethylene, fabric, silicone, polyurethane, silicone-polyurethane copolymers, polymeric rubbers, polyolefin rubbers, elastomers, rubbers, thermoplastic elastomers, thermoset elastomers and elastomeric composites. In one embodiment, the flexibility of the longitudinal element includes movement in a lateral or side to side direction and prevents expanding and/or extension in an axial direction. In some embodiments, all or only a portion of the longitudinal element may have a semi-rigid, rigid or elastic configuration, and/or have elastic properties, such as the elastic properties corresponding to the material examples described above. In some embodiments, the longitudinal element may be compressible in an axial direction.

In assembly, operation and use, spinal correction system **10**, similar to the systems described herein, is employed with a surgical procedure, such as, for example, a correction treatment to treat adolescent idiopathic scoliosis and/or Scheuermann's kyphosis of a spine. In some embodiments, one or all of the components of spinal correction system **10** can be delivered or utilized as a pre-assembled device or can be assembled in situ. Spinal correction system **10** may also be employed with other surgical procedures.

For example, spinal correction system **10** is employed with a surgical treatment for scoliosis correction of an affected section of a spinal column and adjacent areas within a body B of a patient, such as, for example, vertebrae V that includes thoracic vertebral levels T and lumbar vertebral levels L. Body B includes a lateral portion LP and a contra-lateral portion CLP. In one example, thoracic vertebral levels L include an apical portion A, which comprises an apex of a scoliosis curvature and/or deformity. In some embodiments, spinal correction system **10** may be employed with one or a plurality of vertebrae.

In use, to treat vertebrae V, a medical practitioner obtains access to a surgical site including vertebrae V in any appropriate manner, such as through incision and retraction of tissues. In some embodiments, spinal correction system **10** can be used in any existing surgical method or technique including open surgery, mini-open surgery, minimally invasive surgery and percutaneous surgical implantation, whereby vertebrae V is accessed through a mini-incision, or sleeve that provides a protected passageway to the area. Once access to the surgical site is obtained, the particular surgical procedure can be performed for treating the spine disorder.

One or a plurality of percutaneous incisions are made in body B and a cutting instrument (not shown) creates one or a plurality of surgical pathways and/or openings for implantation of components of spinal correction system **10**. The percutaneous incisions are made in tissue of portions LP, CLP and disposed in a plane parallel to a sagittal plane SP, as shown in FIG. **5**, of vertebrae V. The tissue of portions LP, CLP includes soft tissue comprising muscle, ligaments, tendons, cartilage and/or bone. Once access to the surgical site is obtained percutaneously, the components of spinal implant system **10** can be delivered or implanted with portions LP, CLP. A preparation instrument (not shown) can be employed to prepare tissue surfaces of vertebrae V, as well as for aspiration and irrigation of a surgical region.

Pilot holes (not shown) are made bilaterally in vertebrae V for receiving MAS **12**. Shaft **18** of each MAS **12** is inserted, drilled or otherwise fixed to the vertebral levels of vertebrae V. Spinal correction system **10** includes implant supports, such as, for example, extenders and/or reduction instruments **30** that are applied to MAS **12** attached with vertebrae V on contiguous vertebrae, as shown in FIGS. **3-5**. Instruments **30** are oriented for manipulation, alignment and capture of MAS **12**. In some embodiments, one or a plurality of instruments **30** can be applied to a respective concave or convex portion of vertebrae V for performing one or a plurality of steps employing spinal correction system **10**. In one embodiment, instruments **30** are disposed in series along vertebrae V such that an instrument is disposed with each vertebral level of a treated section. In one embodiment, instruments **30** are disposed on alternating and/or spaced apart vertebral levels of vertebrae V such that an instrument is disposed on every other vertebral level. In some embodiments, instruments **30** may be alternated and/or spaced apart over one or a plurality of vertebral levels of a treated section of vertebrae V.

An instrument release **32** of each instrument **30** is manipulated to move leg extensions **34** in an outward direction such that distal engagement parts **36** move outwardly and are disposed in an open position. Distal engagement parts **36** are brought into close proximity with receivers **16** of each of MAS **12** to provide engagement with each of MAS **12**. Instrument release **32** is manipulated such that

leg extensions **34** are moved inwardly and distal engagement parts **36** are disposed in a closed position to capture each of MAS **12** in releasable fixation. Leg extensions **34** define an opening, such as, for example, an elongated slot **38** that is disposed in alignment and communicates with passageway **22** to define a window **40**.

Instruments **30** are applied to MAS **12** attached with levels T on portion LP, which includes a concave portion of vertebrae V. In some embodiments, instruments **30** are applied to MAS **12** attached with levels L on portion LP, which includes a convex portion of vertebrae V. In some embodiments, instruments **30** are applied to MAS **12** attached with levels T on portion CLP, which includes a convex portion of vertebrae V. In some embodiments, instruments **30** are applied to MAS **12** attached with levels L on portion CLP, which includes a concave portion of vertebrae V.

Spinal rod **14** extends between ends **42**, **44** in a configuration for attachment with vertebrae V. Spinal rod **14** includes a portion **46** having a selected curvature. In one embodiment, spinal rod **14** has a concave configuration and is inserted into and provisionally disposed with MAS **12** and attached with levels T on portion LP, which includes a concave portion of vertebrae V.

In one embodiment, spinal rod **14** is sequentially inserted along vertebrae V and attached to MAS **12** at a plurality of vertebral levels. In one embodiment, spinal rod **14** is inserted in a cephalad to caudal orientation, in the direction shown by arrow AA in FIG. **3**. In one embodiment, end **42** may be sharpened to facilitate insertion and movement through body B. In some embodiments, ends **42**, **44** may include a locking element, such as, for example, a notch or groove, for attachment with an inserter **50** to maintain the orientation of spinal rod **14** relative to inserter **50** and/or vertebrae V during insertion and rotation of spinal rod **14**.

Portion **46** is selectively pre-bent by the practitioner for correction of vertebrae V. In some embodiments, a rod template is disposed with body B to create a template for the pre-bent configuration of spinal rod **14** including the selected curvature of portion **46**. In one embodiment, spinal rod **14** includes a pre-bent shape to apply specific corrective forces to the individual vertebral levels of vertebrae V. In one embodiment, the pre-bent configuration of spinal rod **14** and/or the selected curvature of portion **46** is determined by the flexibility of the spinal deformity and/or the amount of correction, translation and rotation of the vertebral levels of vertebrae V in an effort to align and correct the vertebral levels of vertebrae V. In some embodiments, spinal rod **14** and/or the selected curvature of portion **46** may be bent in one, two, or three dimensions depending on the amount of correction for the vertebral levels in the coronal, sagittal, and axial planes of vertebrae V.

Spinal rod **14** is attached with a distal end **51** of inserter **50** for insertion and positioning within body B, as shown in FIG. **5**, and passing spinal rod **14** along instruments **30** and/or MAS **12**. Inserter **50** includes a handle **52** such that spinal rod **14** is manipulated for insertion into body B, as shown in FIG. **3**. End **42** is inserted into body B in a cephalad to caudal orientation, in the direction shown by arrow AA in FIG. **3**, and through a window **40** of a first instrument **30**/MAS **12** attached to a vertebral level V**1**. Spinal rod **14** is moved through window **40** of the first instrument **30**/MAS **12** such that end **42** is sequentially inserted into and through a window **40** of a second instrument **30**/MAS **12** attached to a vertebral level V**2**.

In some embodiments, insertion of end **42** into window **40** of the second instrument **30**/MAS **12** may require spinal rod **14** and/or handle **52** to be rotated, in the direction shown by arrows BB in FIG. **4**, and/or translated, in the direction shown by arrows CC and DD, relative to vertebrae V, due to the pre-bent configuration of spinal rod **14**, the selected curvature of portion **46** and/or the curvature of vertebrae V. In some embodiments, spinal rod **14** and/or handle **52** may be rotated through a range of 0-180 degrees. Spinal rod **14** is similarly moved through windows **40** of third and fourth instruments **30**/MAS **12** such that end **42** is sequentially inserted into and through the windows **40** of the third and fourth instruments **30**/MAS **12** attached to vertebral levels V**3**, V**4**. In some embodiments, insertion of spinal rod **14** is performed percutaneously by manipulating handle **52** in a free hand delivery technique. In some embodiment, movement of spinal rod **14** through windows **40** and/or body B can be monitored using navigation, fluoroscopy imaging techniques and/or tactile feedback.

With inserter **50** attached and spinal rod **14** disposed in windows **40**, as described herein, handle **52** is manipulated and spinal rod **14** is rotated and/or translated to a selected orientation relative to vertebrae V, which includes a selected sagittal and/or coronal rod position relative to vertebrae V, for correction of vertebrae V. Instruments **30** each include reducers **60**, as shown in FIGS. **4** and **5**, configured to dispose spinal rod **14** with receivers **16** of MAS **12**. Each reducer **60** includes a handle **62** manipulable to align reducer **60** with an interior passageway of each of instruments **30**. Reducer **60** has an outer surface **64** that is threaded with an inner surface of each of instruments **30**. Reducer **60** is rotated to translate reducer **60** axially, in a proximal or distal direction relative to instrument **30**. Reducer **60** is translated such that an end surface **66** engages spinal rod **14** in a configuration to move spinal rod **14** distally to drive spinal rod **14** into passageways **22** of receivers **16**.

With inserter **50** attached and spinal rod **14** disposed in windows **40**, as described herein, reducers **64** are manipulated to draw receivers **16** of MAS **12** attached with apical portion A, which includes levels V**1**, V**2**, V**3**, V**4**, up to receive spinal rod **14**, in the direction shown by arrow EE in FIG. **5**. Spinal rod **14** is selectively and provisionally reduced within passageways **22** such that spinal rod **14** is disposed in the selected orientation relative to vertebrae V, for example, in a sagittal plane of vertebrae V offset from plane SP for correction of vertebrae V.

Spinal rod **14**, as shown in FIGS. **6** and **7**, is provisionally seated within receivers **16** connected with apical portion A such that inner surfaces **20** are movable relative to outer surface **24** and receivers **16** are movable relative to shafts **18**. With inserter **50** attached with spinal rod **14** to maintain spinal rod **14** in the selected orientation, instruments **30** are manipulated, in the direction shown by arrows FF. Instruments **30** are movable to rotate receivers **16** about spinal rod **14** such that surface **20** rotates about surface **24**. As surface **20** rotates about surface **24**, receiver **16** pivots and/or rotates about shaft **18** to a movement limit at which point shaft **18**, which are fastened with the vertebral levels adjacent apical portion A on portion LP, is caused to move about spinal rod **14**. As such, manipulation of instruments **30**, which are connected to shafts **18** fastened with adjacent apical portion A, provide a lever configuration or leverage for manipulation and resultant application of one or a plurality of forces and/or moments for application to vertebrae V, for example, a derotation force for a spinal treatment. In some embodiments, rotation of receiver **16** relative to shaft **18** causes apical portion A to move about spinal rod **14** into alignment with the selected orientation and the selected curvature of spinal rod. In some embodiments, movement of shaft **18** and

apical portion A fastened therewith about spinal rod **14** causes apical portion A to move into alignment with the selected orientation and the selected curvature of spinal rod.

A force, in the direction shown by arrows FF, is applied to instruments **30** via manipulation of a practitioner during a surgical treatment, to displace, pull, twist or align vertebrae V to the selected orientation and the selected curvature of spinal rod **14** for sagittal, coronal and/or axial correction. Upon application of derotation forces to vertebrae V to the selected orientation and the selected curvature of spinal rod **14**, as described, set screws are employed to finally lock spinal rod **14** with MAS **12** attached with portion LP adjacent apical portion A.

In some embodiments, intermediate portion **46** may be reduced, as described herein, with MAS **12** fastened with apical portion A and the remaining portions of spinal rod **14** reduced sequentially from portion **46** with MAS **12** fastened with vertebral levels extending in a cephalad and/or caudal direction from apical portion A. In some embodiments, instruments **30** are connected to MAS **12** fastened with vertebral levels extending in a cephalad and/or caudal direction from apical portion A and instruments **30** are manipulated, similar to that described, to create derotation forces and segmentally derotate the vertebral levels extending in a cephalad and/or caudal direction from apical portion A. In such embodiments, upon application of derotation forces to the vertebral levels extending in a cephalad and/or caudal direction from apical portion A to the selected orientation and the selected curvature of spinal rod **14**, as described, set screws are employed to finally lock spinal rod **14** with MAS **12** attached with portion LP adjacent the vertebral levels extending in a cephalad and/or caudal direction from apical portion A.

In some embodiments, a spinal rod **114** (shown in phantom in FIGS. **6** and **7**), having a selected curvature and disposed in a selected orientation relative to vertebrae V, as described herein, is attached with MAS **12** fastened with portion CLP of vertebrae V, similar to the methods described herein, for sagittal, coronal and/or axial correction of vertebrae V.

In some embodiments, reducers **60** may reduce spinal rod **14** with various MAS **12** incrementally, continuously to engagement with spinal rod **14** and/or to disengagement from spinal rod **14**, during the various steps of the correction treatment. In some embodiments, the scoliosis correction method includes repeating the derotation method steps for other vertebrae. In some embodiments, the scoliosis correction method includes repeating the derotation method steps for vertebrae of the lumbar, cervical, thoracic and pelvic regions of a spinal column. In one embodiment, the scoliosis correction method is employed with a correction of a right thoracic adolescent idiopathic scoliosis. In one embodiment, the scoliosis correction method is employed with a correction of a left lumbar scoliosis.

In some embodiments, a guide wire and/or a trocar-cannula assembly may be employed as an instrument for gaining access to the surgical site and/or defining the pedicle trajectory. The guide wire is introduced along the pedicle trajectory before delivering the fasteners. The fasteners are translated over the guide wire to be delivered to vertebrae V. In one embodiment, an interbody implant (not shown) is delivered along a direct lateral surgical approach or pathway adjacent to a surgical site and implanted adjacent selected vertebral levels.

Upon completion of a procedure, described herein, the surgical instruments, assemblies and non-implanted components of spinal correction system **10** are removed and the incisions are dosed. One or more of the components of spinal correction system **10** can be made of radiolucent materials such as polymers. Radiomarkers may be included for identification under x-ray, fluoroscopy, CT or other imaging techniques. In some embodiments, the use of surgical navigation, microsurgical and image guided technologies may be employed to access, view and repair spinal deterioration or damage, with the aid of spinal correction system **10**. In some embodiments, spinal correction system **10** may include one or a plurality of plates, connectors and/or bone fasteners for use with a single vertebral level or a plurality of vertebral levels.

In one embodiment, spinal correction system **10** includes an agent, which may be disposed, packed, coated or layered within, on or about the components and/or surfaces of spinal correction system **10**. In some embodiments, the agent may include bone growth promoting material, such as, for example, bone graft to enhance fixation of the components and/or surfaces of spinal correction system **10** with vertebrae. In some embodiments, the agent may include one or a plurality of therapeutic agents and/or pharmacological agents for release, including sustained release, to treat, for example, pain, inflammation and degeneration.

In some embodiments, the components of spinal correction system **10** may be employed to treat progressive idiopathic scoliosis with or without sagittal deformity in either infantile or juvenile patients, including but not limited to prepubescent children, adolescents from 10-12 years old with continued growth potential, and/or older children whose growth spurt is late or who otherwise retain growth potential. In some embodiments, the components of spinal correction system **10** and methods of use may be used to prevent or minimize curve progression in individuals of various ages.

It will be understood that various modifications may be made to the embodiments disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplification of the various embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

What is claimed is:

1. A method for treating a spine, the method comprising the steps of:

fastening a plurality of fasteners with a lateral portion of vertebrae, each of the fasteners including a first element that defines an implant cavity and a second element configured for penetrating the vertebrae;

providing a longitudinal element including a portion having a selected curvature;

positioning the longitudinal element above the implant cavities;

rotating the longitudinal element about a longitudinal axis defined by the longitudinal element with the longitudinal element positioned above the implant cavities such that the portion is disposed in a selected orientation relative to the vertebrae;

reducing the longitudinal element into the implant cavities after the longitudinal element is rotated such that the portion is in the selected orientation relative to the vertebrae after the longitudinal element is reduced into the implant cavities; and

moving the first element of at least one of the fasteners relative to the second element of the at least one of the fasteners such that the first element of at least one of the fasteners rotates relative to the portion and the second element of at least one of the fasteners moves about the

longitudinal element to derotate the vertebrae while maintaining the portion in the selected orientation relative to the vertebrae.

2. A method as recited in claim **1**, further comprising the step of percutaneously delivering the fasteners adjacent to a surgical site including the vertebrae.

3. A method as recited in claim **1**, further comprising the step of connecting implant supports with the fasteners and the step of positioning includes passing the longitudinal element through the implant supports.

4. A method as recited in claim **1**, further comprising the step of bending the portion to the selected curvature.

5. A method as recited in claim **1**, wherein the selected orientation includes a sagittal plane of the vertebrae.

6. A method as recited in claim **1**, further comprising the step of connecting a surgical instrument with the longitudinal element and the step of reducing includes manipulating the surgical instrument to fix the portion in the selected orientation.

7. A method as recited in claim **1**, further comprising the step of connecting a surgical instrument with the longitudinal element and the step of positioning includes manipulating the surgical instrument to position the longitudinal element above the implant cavities.

8. A method as recited in claim **7**, wherein the surgical instrument includes an inserter configured to percutaneously deliver the longitudinal element with a free hand technique.

9. A method as recited in claim **1**, further comprising the step of connecting first portions of implant supports with the fasteners and the step of reducing includes rotating second portions of the implant supports relative to the first portions such that the second portions translate axially relative to the first portions and engage the longitudinal element thereby provisionally reducing the longitudinal element with the first elements.

10. A method as recited in claim **1**, wherein the step of fastening includes fastening one or more of the fasteners with an apical portion of the vertebrae and the step of reducing includes reducing the longitudinal element with the fasteners fastened with the apical portion, and subsequently reducing the longitudinal element with the remaining fasteners sequentially from the apical portion.

11. A method as recited in claim **10**, wherein the step of reducing the longitudinal element with the remaining fasteners includes sequential reduction from the apical portion in a cephalad and/or a caudal orientation.

12. A method as recited in claim **1**, further comprising the step of connecting implant supports with the fasteners and the step of moving includes manipulating the implant supports to rotate the first elements relative to the portion such that the second elements derotate the vertebrae while maintaining the portion in the selected orientation.

13. A method as recited in claim **12**, wherein rotation of the first elements derotate the vertebrae to correct the vertebrae in a sagittal plane of the vertebrae and/or a coronal plane of the vertebrae while maintaining the portion in the selected orientation.

14. A method as recited in claim **12**, wherein the first element includes an inner surface that defines the implant cavity and the longitudinal element includes an outer surface such that the inner surface rotates about the outer surface.

15. A method as recited in claim **1**, further comprising the step of locking the longitudinal element with the fasteners via coupling members with the portion disposed in the selected orientation.

16. A method as recited in claim **1**, further comprising the steps of fastening one or more of the fasteners with a contra-lateral portion of the vertebrae and disposing a second longitudinal element with the fasteners fixed with the contra-lateral portion.

17. A method for treating a spine, the method comprising the steps of:

fastening a plurality of fasteners with a lateral portion of vertebrae, each of the fasteners including a receiver that defines an implant cavity and a shaft configured for penetrating the vertebrae;

providing a longitudinal element including a portion having a selected curvature;

connecting a surgical instrument to the longitudinal element;

manipulating the surgical instrument to position the longitudinal element above the implant cavities;

rotating the longitudinal element about a longitudinal axis defined by the longitudinal element with the longitudinal element positioned above the implant cavities such that the portion is disposed in a selected orientation relative to the vertebrae;

reducing the longitudinal element within at least one of the implant cavities after the longitudinal element is rotated such that the portion is in the selected orientation relative to the vertebrae after the longitudinal element is reduced into the implant cavities; and

rotating the receiver of at least one of the fasteners relative to the shaft of the at least one of the fasteners such that the receiver of at least one of the fasteners rotates relative to the longitudinal element and the shaft of at least one of the fasteners moves about the longitudinal element to derotate the vertebrae while maintaining the portion in the selected orientation relative to the vertebrae.

18. A method as recited in claim **17**, further comprising the step of connecting implant supports with the fasteners and the step of manipulating includes provisionally reducing the longitudinal element within the implant supports.

19. A method as recited in claim **17**, wherein the surgical instrument includes an inserter configured to percutaneously deliver the longitudinal element with a free hand technique.

20. A method for treating a spine, the method comprising the steps of:

fastening a plurality of fasteners with a lateral portion of vertebrae, each of the fasteners including a receiver having an inner surface that defines an implant cavity and a shaft configured for penetrating the vertebrae, the receiver being rotatable relative to the shaft in a plurality of planes that lie in a cone configuration, wherein one or more of the fasteners are fastened with an apical portion of the vertebrae;

providing a longitudinal element including a portion having a selected curvature;

positioning the longitudinal element above the fasteners;

rotating the longitudinal element about a longitudinal axis defined by the longitudinal element with the longitudinal element positioned above the implant cavities such that the portion is disposed in a selected orientation relative to the vertebrae, the fasteners being disposed with the apical portion;

reducing the longitudinal element into the implant cavities after the longitudinal element is rotated such that the longitudinal element is in the selected orientation relative to the vertebrae after the longitudinal element is reduced into the implant cavities; and

rotating the receivers relative to the portion and the shafts such that the inner surfaces rotate relative to an outer surface of the longitudinal element and the shafts move

about the longitudinal element to derotate the vertebrae while maintaining the portion in the selected orientation relative to the vertebrae.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 9,717,531 B2
APPLICATION NO. : 14/057930
DATED : August 1, 2017
INVENTOR(S) : Anand et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

In Item (72), under "Inventors", in Column 1, Line 2, delete "R" and insert -- R. --, therefor.

In the Specification

In Column 1, Line 4, delete "HELD" and insert -- FIELD --, therefor.

In Column 1, Line 34, delete "of;" and insert -- of: --, therefor.

In Column 5, Line 19, delete "Inc)," and insert -- Inc.), --, therefor.

In Column 5, Line 42, delete "polyiyrosine carbonate, polycaroplaetohe" and insert -- polytyrosine carbonate, polycaprolactone --, therefor.

In Column 6, Line 7, delete "distracters," and insert -- distractors, --, therefor.

In Column 10, Line 36, delete "reducers 64" and insert -- reducers 60 --, therefor.

In Column 12, Line 1, delete "dosed." and insert -- closed. --, therefor.

Signed and Sealed this
Sixth Day of February, 2018

Joseph Matal

Joseph Matal
Performing the Functions and Duties of the
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office